Functional status and walking ability after lower extremity bypass grafting or angioplasty for intermittent claudication: Results from a prospective outcomes study

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Objective: The purpose of this study was the prospective comparison of functional outcomes after lower extremity bypass grafting surgery, angioplasty, or medical management of intermittent claudication.
Methods: The study was designed as a prospective cohort study to compare functional outcomes for patients with interventional management to medical management, including a matched (younger, with more disability) subgroup, followed for a mean of 19 months. Sixteen Chicago-area vascular surgery clinics participated in the study. The subjects were consecutively enrolled patients with an abnormal ankle-brachial blood pressure index (ABI), without signs of rest pain, ulcer, or gangrene, and without prior lower extremity revascularization procedures. The main outcome measures were changes in physical functioning, community walking distance, bodily pain, leg symptoms, and ABI.
Results: Of the 526 study patients, 20% underwent revascularization procedures (60 surgical bypass grafting and 44 angioplasty only). The mean ABI improved significantly for the patients who underwent bypass grafting surgery (0.20; $P < .001$) and modestly for the patients who underwent angioplasty (0.09; $P < .05$). Patients undergoing bypass grafting and angioplasty maintained highly significant ($P < .001$) improvements in mean physical functioning, (17%, 14%), bodily pain (18%, 13%), and walking distance (28%, 27%) scores and reported greater leg symptom improvement. The results were far superior for the patients with greater improvement in ABI. The conditions of the 277 unmatched patients who underwent medical management declined on all outcome measures, and the conditions of the 145 matched patients who underwent medical management improved 5% ($P < .001$) on walking distance score. Eighteen percent of the study patients failed to complete the full study follow-up period.
Conclusion: Most of the functional improvement achieved by patients who underwent interventional management appears to be related to improved patency rather than to selection bias or placebo effects. The functional gains were approximately half those often reported for patients for hip arthroplasty and similar to patients who undergo elective coronary angioplasty. (J Vasc Surg 2000;31:93-103.)

Vascular surgeons are seeing increasing numbers of older patients who have walking impairment related to intermittent claudication, a manifestation of mild to moderate lower extremity arterial occlusive disease. Although lower extremity bypass grafting surgery and angioplasty were traditionally reserved for patients with limb-threatening ischemia, patient reports of significant activity limitation and reduced quality of life have become increasingly important indications for their use. Overall arterial

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Table I. Sample descriptive statistics at enrollment by patient treatment group

	All study patients (n = 526)	*Medical management (n = 277)*	*Matched medical management (n = 145)*	*Bypass grafting surgery (n = 60)*	*Angioplasty (n = 44)*
Sociodemographic characteristics					
Mean age (SD)	69 (10)	71 (9)	66 (8)	66 (9)	63* (11)
Male sex	421 (80%)	215 (78%)	124 (86%)	46 (77%)	36 (82%)
African-American race	87 (16%)	61 (22%)	19 (13%)	14 (23%)	5 (11%)
Married	315 (59%)	164 (59%)	88 (61%)	33 (55%)	30 (68%)
Education > high school	401 (76%)	214 (77%)	104 (71%)	45 (75%)	38 (86%)
Work full or part time	109 (21%)	61 (22%)	19 (13%)	13 (22%)	16† (36%)
VA clinic site	270 (51%)	129 (47%)	100 (69%)	26† (43%)	15† (34%)
Academic office site	138 (26%)	78 (28%)	22 (15%)	19† (32%)	19† (43%)
Community office site	118 (22%)	70 (25%)	23 (16%)	15 (25%)	10 (23%)
Health status					
Heart disease	246 (47%)	120 (43%)	76 (52%)	30 (50%)	20 (45%)
Diabetes	176 (33%)	87 (31%)	57 (39%)	18 (30%)	14 (32%)
Hypertension	364 (69%)	179 (64%)	111 (77%)	44 (73%)	30 (68%)
ABI < 0.5	135 (25%)	63 (23%)	32 (22%)	33† (55%)	6 (14%)
No / mild comorbidity	183 (35%)	102 (53%)	39 (27%)	20 (33%)	22* (50%)
Moderate comorbidity	163 (31%)	93 (34%)	43 (28%)	19 (32%)	8 (18%)
Severe comorbidity	180 (34%)	82 (30%)	63 (43%)	21 (35%)	14 (32%)
Current smoker	148 (28%)	63 (23%)	49 (34%)	21 (35%)	15 (34%)
Exercised regularly	171 (33%)	114 (41%)	37 (25%)	9 (15%)	11 (25%)
Pentoxifylline	86 (16%)	50 (18%)	22 (15%)	10 (17%)	4 (9%)
Lipid-lowering drugs	151 (29%)	78 (28%)	42 (29%)	16 (27%)	15 (34%)
Leg symptoms					
Duration of leg symptoms > 2 years	302 (57%)	163 (59%)	83 (57%)	38 (63%)	18 (41%)
Severe or very severe leg symptoms	220 (42%)	52 (19%)	93 (64%)	46 (77%)	29 (66%)
Prior willingness to undergo procedure	254 (48%)	73 (26%)	106 (73%)	44 (73%)	31 (71%)
Died during follow-up period	40 (8%)	25 (9%)	13 (9%)	1 (1%)	1 (2%)
Attrition					
Mean follow-up period (months; SD)	19 (4)	18 (4)	19 (4)	20* (4)	21* (4)
Lost to follow-up examination (all causes)	97 (18%)	52 (19%)	34 (23%)	7 (12%)	4* (9%)

VA, Veteran's Affairs; *ABI*, ankle-brachial index.
*$P < .05$, with χ^2 test or *t* test, bypass grafting surgery or angioplasty versus matched medical management.
†$P < .001$, with χ^2 test or *t* test, bypass grafting surgery or angioplasty versus matched medical management.

patency and limb salvage outcomes have been documented at academic centers,[1] but there are few published data that specifically pertain to functional outcomes after lower extremity revascularization procedures for disabling claudication.[2-4] Given the risk of significant mortality, morbidity, complications, and cost, the use of invasive procedures for disabling intermittent claudication remains controversial.[5-7]

Lower extremity surgical or endovascular procedures are frequently requested by patients with disabilities who are frustrated with the traditional medical management of leg symptoms. There is agreement that patients with claudication are likely to benefit from aggressive medical management of comorbid conditions and smoking cessation,[8] particularly because they are at high risk for coronary and cerebrovascular disease events.[9] The Food and Drug Administration–approved rheologic agent pentoxifylline is often prescribed for patients with claudication, and cilostazol, a phosphodiesterase-II inhibitor, has recently received conditional Food and Drug Administration approval, but there is no consensus on whether drug therapy provides clinically meaningful benefits.[10] Structured, usually hospital-based exercise and strength training programs have often been found to be beneficial (whether in place of or in conjunction with interventional management).[11] However, exercise program evaluations have been mostly short term (often 6 months or less) and inherently involve selected patients who are physically (and financially) capable of regular attendance.

The purpose of this prospective, observational study was the examination of change in 18-month measures of patient self-reported physical functioning, community walking distance, bodily pain, and leg symptoms, which are the most important endpoints in the evaluation of treatment options for patients with intermittent claudication. In addition, a patient's ankle-brachial index (ABI), a measure of the ratio of resting ankle systolic blood pressure to pressures in the brachial arteries, was measured to characterize the hemodynamic changes and the

Table II. Baseline and 18-month follow-up physical functioning, walking distance, bodily pain, and ankle brachial index change scores and effect size* by patient group

	Medical management (n = 277)	*Matched medical management (n = 145)*	*Bypass grafting surgery (n = 60)*	*Angioplasty (n = 44)*
SF36 physical functioning score				
Baseline mean (SD)	55 (20)	38 (20)	32 (17)	42 (20)
Follow-up period mean (SD)	53 (22)	40 (20)	49 (26)	56 (20)
Change score mean (SD)	–2 (19)	3 (23)	17† (26)	14† (21)
Effect size	–0.1	0.12	0.66	0.65
WIQ walking distance score				
Baseline mean (SD)	0.45 (0.26)	0.19 (0.17)	0.14 (0.14)	0.20 (0.18)
Follow-up period mean (SD)	0.43 (0.25)	0.24 (0.20)	0.43 (0.32)	0.48 (0.28)
Change score mean (SD)	–0.02 (0.21)	0.05† (0.17)	0.28† (0.32)	0.27† (0.28)
Effect size	–0.11	0.31	0.90	0.98
SF36 bodily pain score				
Baseline mean (SD)	60 (21)	45 (24)	39 (18)	43 (25)
Follow-up period mean (SD)	59 (20)	50 (21)	57 (23)	56 (20)
Change score mean (SD)	–1 (19)	5‡ (23)	18† (26)	13† (21)
Effect size	–0.04	0.2	0.69	0.6
Lowest leg ABI				
Baseline mean (SD)	0.59 (0.15)	0.61 (0.16)	0.49 (0.17)	0.63 (0.14)
Follow-up period mean (SD)	0.58 (0.17)	0.59 (0.19)	0.69 (0.28)	0.72 (0.20)
Change score mean (SD)	–0.01 (0.14)	–0.02 (0.16)	0.20† (0.25)	0.09‡ (0.18)
Effect size	–0.06	–0.12	1.17	0.64

WIQ, Walking Impairment Questionnaire; *ABI,* ankle-brachial index.
*Effect size = (mean follow-up period – mean baseline) / SD of baseline.
†$P < .05$, within group-paired Wilcoxon signed rank sum test or *t* test.
‡$P < .001$, within group-paired Wilcoxon signed rank sum test or *t* test.
All comparisons between matched medical and bypass or angioplasty groups, $P < .05$.

severity of vascular disease. Although they are representative of only one segment of the large and growing population of older patients with peripheral vascular disease, most of whom report atypical leg pain or remain asymptomatic,[12] these results should be broadly generalized to referred patients with mild to moderate vascular disease who contemplate a more aggressive specialty treatment of leg pain produced after walking short distances.

METHODS

Patient sample and study protocol. All the study patients were enrolled from 1993 to 1995 at visits to one of the 16 participating Chicago-area academic (n = 5), community (n = 8), or academically-affiliated Veteran's Affairs (VA; n = 3) clinics. The details about the participating investigators, the enrollment procedures, and the follow-up examination protocol have been previously published.[13] Institutional Review Board approval was obtained at all the participating hospitals, and all the patients signed informed consent forms.

At enrollment, all the patients had an abnormal ABI[14] and were without prior lower extremity revascularization procedures or symptoms of limb-threatening disease, such as rest pain, gangrene, or skin ulcers. To maximize the willingness to enroll and maintain contact with this geographically and demographically diverse patient sample, the follow-up examination was conducted via three sequential, no-cost home visits by project home health nurses at 6-month intervals from enrollment. With portable Doppler scan equipment, the project nurses conducted in-home lower extremity blood pressure examinations scheduled to coincide with the completion of mailed health status questionnaires.[15] ABI measurement was made on the basis of the lowest leg mean of dorsalis pedis and posterior tibial pressures indexed to the highest of the two brachial pressures.

Patient age, sex, race, education, marital status, medication use, smoking and exercise habits were obtained at enrollment by project coordinators at each office or clinic site. The comorbid conditions at enrollment were categorized as having a mild, moderate, or severe impact on functional status on the basis of the most severe of 15 self-reported chronic conditions.[16] Severity classification (mild, moderate, severe) of comorbid conditions was empirically derived from previously published analyses of the effect of comorbid conditions on physical functioning and walking impairment.[3,13]

Study outcomes. The primary study outcome was

Table III. Results for technically successful versus unsuccessful procedures (n = 104)

	ABI change > 0.1 (mean [SD])	*ABI change < 0.1 (mean [SD])*
Bypass grafting surgery	n = 37	n = 23
SF36 physical functioning score	28 (23)	–0.8 (18)
WIQ walking distance score	0.43 (0.27)	0.01 (0.23)
SF36 bodily pain score	25 (24)	5 (24)
ABI	0.36 (0.15)	–0.01 (0.12)
Angioplasty only	n = 22	n = 22
SF36 physical functioning score	20 (23)	7 (17)
WIQ walking distance score	0.35 (0.28)	0.20 (0.26)
SF36 bodily pain score	12 (24)	13 (18)
ABI	0.23 (0.11)	–0.01 (0.01)

ABI, Ankle-brachial index; *WIQ,* walking Impairment Questionnaire.

change in the SF36 Health Status Survey physical functioning (PF) score, on the basis of patient ratings of difficulty in vigorous and moderate activities (lifting or carrying, climbing stairs, bending, kneeling or stooping, walking three distances, and bathing or dressing).[17] The 10-item scale is scored from 0 (worst, greatly limited in all 10 items, including walking one block) to 100 (best, not limited at all for all 10 items, including walking more than a mile). SF36 PF scores have been found to be well correlated (r = .68) with 6-minute walk test results for patients with claudication who are undergoing medical management.[18] Although only 16% of the general US population with PF scores between 30 and 39 report being able to walk one block without difficulty, this percentage grows to 50% for people with scores in the 50 to 59 range and to 79% for people with scores between 60 and 69.[17]

The secondary treatment outcomes included change in the claudication-specific Peripheral Arterial Disease Walking Impairment Questionnaire (WIQ), a measure of pain-free community walking distance previously validated with correlations with peak treadmill walking time.[19] The WIQ score reflects a patient's ratings of four degrees of difficulty in walking up to seven distances (50 feet to five blocks), scaled from 0 (worst, cannot walk indoors) to 1.0 (best, no difficulty walking five blocks). The other outcomes included change in the SF36 bodily pain score (on the basis of two Likert scale items rating severity of bodily pain during the previous 4 weeks) and change in a patient's lowest leg ABI. The ABI was initially measured at the participating hospital blood flow laboratories, and follow-up ABI was computed from the most diseased leg at baseline. Finally, the study patients were asked to rate the severity of the leg symptoms and how much more active they would be if they were free of leg symptoms.

Any subsequent hospitalizations were self reported. The relevant medical records were reviewed to validate the patient reports of endovascular or surgical procedures. For the patients who underwent procedures (or other hospitalizations), the home visits were rescheduled for at least 3 months after discharge to avoid early post-hospital recovery periods. Death information was verified with a search of the National Center for Health Statistics National Death Index Plus for 1994 to 1996.

Treatment groups, selection bias, and attrition. Treatment selection differences inevitably bias observational comparisons of patient outcomes. In this study, approximately 65% of the patients who were managed interventionally as opposed to only 50% of all the patients who were managed medically indicated that urging by their "regular, primary care" doctor was an important reason for making the appointment at which they were enrolled for the study. Prior research on study patients who initially underwent surgery or angioplasty has revealed that ABI, leg symptom severity, walking distance, and the degree of prior willingness to have a hospital procedure to improve walking ability all predicted subsequent interventional management.[20] To estimate the influence of these selection effects, key treatment selection variables were used to designate the most comparable subgroup of patients for medical management. A computer algorithm was used with empirically derived cutoff values for seven baseline variables that predicted the highest likelihood of interventional management (age, prior willingness to undergo a hospital procedure, baseline SF36 PF and bodily pain scores, WIQ walking distance score, leg symptom severity, and ABI).[20] This selection algorithm was applied to the medical management group as a whole to simultaneously identify a younger, but functionally much more limited, comparative subgroup of patients for medical management. This comparison group provided the most appropriate possible test of the extent to which differences in outcomes were related to treatment rather than placebo or regression to the mean effects.[21]

Table IV. Regression analysis results: baseline and treatment characteristics as predictors of follow-up SF36 physical functioning score (n = 526; R^2 = .44)

	Coefficient	*SE*	*P value*
SF36 physical functioning score	0.4	0.04	<.0001
WIQ walking distance score	17.2	3.9	<.0001
SF36 bodily pain score	0.1	0.04	.04
ABI	4.8	5.3	.36
Severe or very severe leg symptoms	–1.9	1.9	.31
Duration of symptoms > 2 years	–2.3	1.6	.14
Age	–0.4	0.09	.0001
Male sex	2.6	2.3	.26
African-American race	–4.1	2.2	.06
VA clinic enrollment	–6.2	2.3	.006
Academic office enrollment	1.3	2.2	.56
> High school education	1.9	1.8	.29
Married	–4.0	1.7	.01
Work full or part time	–0.2	2.1	.93
Severe comorbidity	–5.8	1.9	.002
Moderate comorbidity	–2.6	1.9	.18
Exercise regularly	2.9	1.7	.20
Current smoker	–2.0	1.8	.26
Angioplasty patient	9.7	3.2	.002
Bypass grafting surgery patient	12.1	3.0	.0001
Matched medical patient	1.5	2.2	.49
Constant	50.6	9.5	<.0001

WIQ, Walking Impairment Questionnaire; *ABI,* ankle-brachial index; *VA,* Veteran's Affairs.

With respect to patients who underwent interventional management, the outcomes for the patients who underwent angioplasty alone were analyzed separately from the outcomes of the patients who underwent surgical bypass grafting procedures. When a patient underwent both procedures (whether staged within a single admission or in a subsequent hospitalization), the patient was classified as a bypass grafting patient, for the definitive revascularization procedure. This approach created the following four separate patient groups: matched medical management, unmatched medical management, angioplasty only, and bypass grafting surgery.

To capture the effects of potentially multiple interventions over time, the study design was based on time from enrollment, not from a given (first) procedural intervention. Single baseline and follow-up measures therefore were computed for all the study patients, rather than life-table methods, which are appropriate for the continuous follow-up of a discrete procedure. For patients who underwent interventional management, either a single pre-procedure observation or the mean of multiple pre-procedure observations was compared with either a single follow-up observation or the mean of multiple follow-up observations. For patients who underwent medical management, the baseline value was the enrollment value and the follow-up value was computed as the mean of (up to three) follow-up observations. With the exclusion of post-hospitalization recovery periods, any post-intervention follow-up results recorded at second, third, or fourth visits are averaged to provide a mean endpoint to compare with baseline. The follow-up measures thus average the patient's ups and downs, giving "credit" for subsequent, secondary procedures that preserve function, or conversely, reducing overall benefits when an initially successful procedure failed.

Patency (primary or assisted) was defined as an overall change in the ABI of more than 0.1. Given the averaging formula for multiple examinations, this measure represents a conservative definition of technical procedural success.[8] It was expected that a substantial number of enrolled patients might die or become incapacitated. For these patients, the last observed functional outcomes were analyzed.[22]

Statistical analysis. The changes between baseline and follow-up measures within each patient group were analyzed with paired, two-tailed *t* tests for the ABI and SF36 scores and the paired Wilcoxon signed rank sum test for the WIQ walking distance score. Effect sizes were calculated as the mean follow-up period minus the mean baseline divided by the standard deviation of the baseline to provide a unit of measure-free estimate of within-group change.[23] Because all the change scores were normally distributed, two-tailed *t* tests were used to test the significance of the differences. The χ^2 test

was used to test the differences in the proportion of patients in each group whose conditions improved (as opposed to stayed the same or worsened) from baseline to follow-up examination on individual leg symptom severity items. Finally, ordinary least squares multiple regression analysis was used to test the effect of treatment group status (bypass grafting surgery, angioplasty, matched and unmatched medical management) in the prediction of follow-up SF36 PF scores controlling for patients' baseline PF score, walking distance, bodily pain, ABI, age, sex, race, employment, marital status, clinic enrollment site (VA, community, academic), severity of comorbid conditions (three levels), smoking and exercise habits, leg symptom severity, and duration of claudication symptoms (greater or less than 2 years).

RESULTS

Interventional procedures. A total of 526 patients completed at least one study follow-up examination visit. During the mean 19-month period from enrollment to the last follow-up examination, a total of 104 study patients (20%) underwent lower extremity bypass grafting or angioplasty procedures. Of these 104 patients, 17 underwent both surgical and endovascular procedures and were therefore analyzed with the 43 other patients for surgical bypass grafting (for a total of 60 patients for bypass grafting). An additional 44 patients underwent angioplasty procedures only. Of the 61 total angioplasty procedures, 40 were at the iliac level, and, of the 21 at the femoral level, only three extended to the popliteal level. The bypass grafting procedures included 36 femoropopliteal, 10 aortobifemoral, 10 femorofemoral, two aortobiiliac, one aortobipopliteal, and one profundaplasty procedure. The mean time from enrollment to lower extremity revascularization procedure was 5.4 months, and two thirds of all the patients underwent procedures within 6 months of enrollment and more than 80% within 1 year. The 32 patients who underwent diagnostic lower extremity angiography but did not have angioplasty or bypass grafting surgery are grouped with other patients for medical management.

Matching criteria and baseline differences in treatment groups. A total of 145 patients for medical management were identified with the matching of criteria cutoffs as the patient group that most closely resembled the patients for interventional management at enrollment. No statistically significant mean differences between the patients who were matched and interventionally managed existed for six of the seven matching variables (age, baseline SF36 PF, bodily pain scores, WIQ walking distance score, willingness to undergo a procedure, and leg symptom severity). The patients who underwent interventional management, notably those who underwent bypass grafting procedures, had a significantly lower mean ABI at baseline (0.55 vs 0.60; $P = .005$). As compared with the other patients who underwent medical management and as intended by the matching criteria, the matched patient group was younger, rated the leg symptoms as severe (64% vs 18%), and were much more willing to undergo a procedure for the legs (73% vs 26%). Although unintended by the matching algorithm, the patients who were matched and medically managed were more commonly enrolled at the VA sites (69% to 47%). More than 40% of the 277 unmatched patients reported engaging in "regular physical exercise" at baseline as compared with only 25% of the patients who were matched and medically managed and the patients for angioplasty and only 15% of the patients for bypass grafting surgery.

Table I illustrates the full range of baseline differences in sociodemographic, medical history, medication use, leg symptom significance, and study attrition among the four separate treatment groups. As is consistent with the younger age, the patients for angioplasty were significantly more likely to be working full or part time at enrollment (36%) and there were more patients (50%) who reported mild or no comorbid conditions. The patients who underwent bypass grafting surgery and angioplasty were disproportionately enrolled at academic, rather than VA, sites. The bypass grafting surgery group had a significantly higher proportion of patients (55%) with the lowest ABI (<0.05). The prevalence of patient self-reported hypertension, diabetes, and heart disease (as indicated by a history of heart failure, angina, previous myocardial infarction, previous coronary artery bypass grafting surgery, or angioplasty) was roughly equivalent in each of the four groups.

Few significant differences in medication use existed between groups. At enrollment, 16% of the study patients reported regular use of pentoxifylline and 28% used lipid-lowering drugs (18% used 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors). A total of 71% of the study patients were taking aspirin regularly, and an additional 7% were taking warfarin sodium. Other widely prescribed drugs included diuretics (29%), angiotensin-converting enzyme inhibitors (35%), vasodilators (12%), nitrates (19%), calcium channel blockers (43%), and beta blockers (21%). Among the 105 female patients, 21 (20%) reported taking estrogen.

Attrition and disease progression. A total of 97 study patients (18%) failed to complete the full study follow-up period. Of these, 40 patients (8%) died. The death certificate data indicated that 23 deceased patients had died of cardiovascular disease causes (57%) and that 30% of the remaining deaths were attributed to cancer and pneumonia. There were only two deaths among the bypass grafting and angioplasty groups (unrelated to procedures). A total of 16 patients (3%) became incapacitated and were unable to continue study participation, including four patients who had disabling strokes and three patients with disabling cardiac events. Twenty-five patients (5%) were lost to follow-up examination, including four patients who were placed in nursing homes, and 16 additional patients (3%) refused further participation after one or more follow-up visits. Attrition was heaviest in the medically managed groups, as compared with the bypass grafting or angioplasty groups (20% vs 11%). Five patients underwent below-knee amputations (three after procedures and two while undergoing medical management), and there were three toe amputations. It was impossible to determine whether the below-knee amputations after procedures by 4 and 5 months, respectively, were iatrogenic or related to underlying disease progression. The mean overall study follow-up time was greatest for the patients who underwent interventional management, in part because of the need to schedule home visits around periods during and shortly after hospitalization and in part because of lower study attrition.

Comparisons of baseline and follow-up outcome measures. Table II provides comparisons of mean change scores, effect sizes, and results of paired within-group significance tests. The scores are displayed as baseline (enrollment or mean of pre-procedure intervals) and follow-up (mean of all post-enrollment or post-procedure intervals) for each continuous outcome measure. Effect size calculations indicate a three-fold to five-fold difference in the magnitude of change between the matched medically and interventionally managed groups. The patients who were unmatched and underwent medical management had non-significant declines on each of the four outcome measures. The patients who were matched and underwent medical management had small, non-significant improvements in mean PF and bodily pain scores, a modest but significant 5% ($P < .001$) improvement in mean walking distance, and little change in mean ABI. In contrast, the patients who underwent bypass grafting and angioplasty had much larger overall improvements ($P < .001$) in mean SF36 PF (17%, 14%), bodily pain (18%, 13%), WIQ walking distance (28%, 27%), and ABI (0.20, 0.09).

Mean outcomes were plotted for each study interval and revealed a similar pattern. Virtually all the gains for the patients who underwent interventional management occurred within the first 6-month interval (when two thirds of all procedures occurred) and were maintained at the same higher level at each subsequent follow-up examination. In comparison, these line graphs were virtually flat across all three 6-month study follow-up intervals for the two medically managed groups, indicating no overall mean change from baseline enrollment for these patients.

These results were consistent with the proportion of each group that reported improvement of at least one Likert scale level on leg symptom questionnaire items. The patients for bypass grafting surgery and angioplasty reported the largest improvement on leg symptom severity (57%, $P < .05$; 34%, NS) and activity limitation (32%, $P < .05$; 43%, $P < .001$) items. A nonsignificant but substantial number of matched and unmatched patients who were medically managed also reported some improvement from baseline leg symptom severity (14%, 32%) and activity limitation (13%, 14%).

Patency results for patients for interventional management. Table III presents the results separately for the patients who underwent interventional management who had a change in ABI of more than 0.1. There was a huge improvement in functional and pain outcomes for the patients who underwent more successful procedures (62% of patients for bypass grafting and 50% of patients for angioplasty). The 28% PF score (and 0.36 ABI) improvement for patients who underwent successful bypass grafting contrasts with no improvement among the patients with poorer patency outcomes: the patients who underwent successful angioplasty had three times the functional improvement as others. It should be noted that change in ABI may understate overall hemodynamic improvement for some patients who undergo more proximal (iliac) revascularization procedures. The correlation between ABI and PF change for patients who underwent interventional management was $r = 0.45$ ($P < .001$).

Regression results. Table IV presents regression analysis results that test the effects of bypass grafting surgery, angioplasty, and matched (as compared with unmatched) medical management on follow-up PF score. These results illustrate the overall effects of the treatment group controlled for the full range of patients' baseline functional, medical, and sociodemographic characteristics. Regression coefficients

reflect predicted points of follow-up PF score positively or negatively associated with each variable.

Bypass grafting surgery was associated with a 12% improvement ($P = .0001$) and angioplasty with a 9.7% improvement ($P = .002$) in follow-up SF36 PF scores as compared with unmatched medical management. The matched patients were associated with an insignificant 1.5% difference from the unmatched patients. The only significant positive predictors of follow-up SF36 PF were baseline SF36 and WIQ walking distance scores. The significant predictors of declining function included age (–0.4 points per additional year of age; $P = .0001$), severe comorbidity as compared with no or mild comorbidity (–5.8 points; $P = .002$), VA clinic enrollment as compared with community office enrollment (–6.2 points; $P = .006$), and being married at baseline (–4.0 points; $P = .01$).

DISCUSSION

This study showed significant improvements in self-reported physical functioning, walking distance, bodily pain, ABI, and leg symptoms for patients with claudication who underwent lower extremity bypass grafting surgery and angioplasty. The patients who underwent invasive procedures had significantly better functional outcomes than the small improvement seen in the patients who underwent medical management who were most severely impaired at baseline. The gains made by patients for interventional management generally extended over the full follow-up period, persisted after controlling for a number of significant baseline covariates in multiple regression analyses, and were associated with improvement in lower extremity blood flow. These gains were concentrated among the patients with the most successful technical outcomes.

The largest functional effects in the medical outcomes literature are associated with total hip or knee arthoplasty for osteoarthritis. The 1-year mean SF36 PF improvement for these patients typically ranges between 20 and 30 points.[24] The gains in PF score reported here for patients who underwent interventional management (17.1 for bypass grafting and 13.7 for angioplasty) are slightly lower than the 19-point change in PF found 6 months after elective coronary angioplasty.[25] However, although the patients for coronary angioplasty had a pre-procedure mean PF score of 59.0, the patients for interventional management in this study had a mean baseline of 36.2. The national PF average for the general US population aged 65 years and more is 69.4.[17] Because the ability to walk is such a critical predictor of subsequent disability, physical functioning improvements at the lower end of the clinical spectrum may be even more important than similar improvements at the higher end of the functional spectrum.[26,27]

The results of this study support prior findings on the functional benefits of vascular surgery.[28] In 1989, Lundgren et al[2] found significant functional improvements associated with lower extremity bypass grafting surgery (with and without an exercise program) versus exercise alone for a randomized sample of 75 patients with claudication in Sweden. At 1 year, 75% to 90% of patients for surgical treatment had maximum walking distances greater than 600 meters as compared with only 10% to 20% of the exercise-only group. Currie et al[4] reported a 3-month follow-up period for selected English patients who underwent lower extremity bypass grafting surgery (n = 34), angioplasty (n = 74), or exercise-only therapy (n = 78). The mean improvement in SF36 PF score for the patients for bypass grafting surgery in this study was equivalent to the 18-point gain reported for the English patients for bypass grafting surgery. The gain associated with angioplasty in this study was somewhat less than the 18-point 3-month gain of the English patients, and the 3-point gain for the English exercise group was equivalent to the results for the patients for medical management studied here.

Several important methodologic limits of this uncontrolled, hypothesis-generating study should be emphasized. First, as is clearly indicated by the differing rates of study attrition, there were important and unmeasured differences that determined which enrolled patients subsequently underwent procedures. The study was designed to capture the usual and typical care at more than a dozen participating institutions and includes the results of procedures subsequently performed at other, non-study hospitals. Whereas the failure rates reported here reflect poor performance in comparison with published academic series, they may unfortunately be more representative of results across the broad range of area practice.

Perhaps most importantly, the outcomes are presented here as differences in group means, the standard approach to measuring differences between systems and providers of care in observational research. This obscures the important predictors of individual patient outcomes within treatment groups (eg, for patients whose surgical or endovascular treatment ultimately failed or for some patients whose conditions improved significantly without hospital proce-

dures). A validated, risk-adjusted regression model could provide a valuable prognostic tool for informing patients about their probabilities of specific functional outcomes. The results presented here are a first step in providing potentially important information for clinicians seeking to advise patients about the appropriateness and likely benefit of interventional management of disabling claudication, a condition destined to be increasingly common among the older population of the next century.

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DISCUSSION

Dr John M. Porter (Portland, Ore). I congratulate Dr McCarthy on his excellent presentation and Dr Feinglass, the senior author of the manuscript. This is another in a series of papers from Northwestern, and now from Rush, attempting to analyze the outcome of claudication treatment in terms of the patient-completed questionnaires that cover a variety of areas, such as social function, general body strength, ability to walk, etc. This is a combination of outcomes that I refer to as the "feel-good" outcomes. I am generally concerned about the ability of patient-administered questionnaires to assess the outcome

of almost anything, especially vascular surgery. All of these tests have been validated, but one has to make sure that one understands the meaning of the word validate. It simply means that someone, somewhere, did some sort of objective study that purported to correlate to some degree with the questionnaire. It may not be as impressive as it sounds.

There are two potential problems with this manuscript, and the author has addressed these. In the first place, the ankle-brachial index increase in the surgery patients was only 0.2 and in the angioplasty patients was less than 0.1. These increases are virtually within the error of repeat ankle-brachial index observations and by themselves do not inspire confidence. I do believe the subgroup analysis, however, helps that considerably. The fact that the patent repair patients had a higher score than the occluded repair patients is reassuring.

However, we are left with a problem that the patients who agree to undergo invasive therapy were likely a different group from those who did not. Hence, the haunting doubts about flawed study design. This could only be examined in a prospective randomized trial in which some patients are randomized to invasive treatment and some are not. This would be very difficult. I would like the author to comment on this potential for the future.

And this brings me to my final point, which is what is the optimal role of invasive therapy for the treatment of claudication? Many of the older members of the audience were brought up on the notion that surgery and its associated risks should be taken very seriously and offered only to individuals with persuasive indications. This and other studies, however, may be interpreted as suggesting that this basic tenet of vascular surgery be reexamined. If the most important outcome of treatment is the "feel-good" score or some modification thereof and we have available such easy treatments as angioplasty, perhaps we should let down the barriers and begin performing angioplasty on everyone, as appears to be happening in certain centers in this country presently. When the angioplasty fails, as it always does, we could simply perform angioplasty again. If a few limbs are lost along the way and healthcare costs escalate, this may be accepted as the price that one has to pay. This new trend concerns me. I do suggest to the upcoming generations that surgical principles that have stood the test of time should be dismissed with great caution. Invasive treatment of small aneurysms, moderate intermittent claudication, and 50% carotid stenosis will never appeal to me.

I appreciate the willingness of the Society to allow me to ramble on. Thank you.

Dr Walter J. McCarthy, III. Thank you, Dr Porter. Dr Porter's somewhat irascible comments do not reveal the fact that during the last few weeks he has reviewed our manuscript and helped us substantially with some of the data analysis. In fact, some of the conclusions that I was able to make today come directly from his own imagination.

The term "feel-good" score might be fairly close to the truth. For many conditions that we treat, the way the patients feel probably is the bottom line, as in the cases for claudication.

The validation of the SF36 actually has been tremendously extensive. The last number of different diagnoses that have been addressed by the SF36 that I know of is 153, ranging from hip replacement to vision dysfunction to urinary tract problems. There have been literally thousands of papers submitted with the SF36, so that you can compare the reproducibility of scores between different papers. We can say, for example, that the usual improvement of the functional score after total hip replacement is in the 20s and 30s, and in the present study involving patients who have undergone correction of their arterial stenosis with bypass grafting, our improvement was 28. We are right up there with the level of the highest increase ever reported in the physical functioning score.

Dr Porter's comment about the small ankle brachial index change that we all recognize as insignificant when a single patient comes back to the blood flow laboratory and has an increase or decrease of only 0.1 is completely different in a large group of patients in which a mean has changed by the same amount. When you have a large group of patients, this mean difference becomes a very powerful statistical change.

Selection bias is what Dr Porter was concerned about in a study like ours, which is nonrandomized. Selection bias always rears its ugly head, and what we tried to do was to pick out a matched medical group. We selected from our medical group patients who had characteristics similar to the interventionally managed patients. This control group had minimal changes in their functional status over time. In the Veteran's Affairs system, it turns out that we are all conservative with the management of claudication, and many of the Veteran's Affairs patients probably would have been treated with intervention if they had been seen in different settings.

Dr Porter. Any chance of a randomized study in there somewhere?

Dr McCarthy. You know, we have thought about doing a randomized study. I have written a proposal for such a study in the Veteran's Affairs system, but it has not been submitted.

Dr Porter. Do you think we should lower the barriers for the treatment of claudication? I am serious about that one.

Dr McCarthy. Well, the question is the risk. We have shown that there is benefit. There are two questions really—the cost and the risk. We do not know exactly what the risk is. In our group, most of the patients were managed conservatively. Only 20% of the patients were treated for their claudication. In some clinics, as you said, who knows how many patients, perhaps more than half or even more than two thirds, are treated with intervention. In our group, in which 20% were treated, there were five lower limbs lost from 526 patients—more than one thousand limbs at risk over the 18-month follow-up period. Two of those cases were patients who had been in the medical group and were so debilitated that when they had increasing limb ischemia they ended up having a primary amputation. One patient underwent a femoropopliteal bypass grafting procedure and then a year later ended up with an amputation. Two other patients had rest pain develop, underwent distal bypass grafting, and eventually lost their limbs. So, all told, there was not much

carnage related to the interventions in this group. Should we lower the barriers of treatment? This paper does not solve that problem. It simply shows that patients carefully, and I believe conservatively, selected for treatment by a sophisticated medical community do have benefit after treatment and have little risk of limb loss as the result of intervention.

Dr Jack L. Cronenwett (Lebanon, NH). I enjoyed your paper and applaud your application of this extra dimension to the analysis of the outcome of these patients. I have two questions.

First, if I interpreted your SF36 scores correctly, it looked as if they were lower initially for the group of patients who were treated surgically, implying that those patients had more severe problems to begin with. My question is, when you analyze the subsequent change in an SF36 score, is it the absolute change that is important or is it the relative change? In other words, if a patient improves from a score of 20 to 40, is that a two-fold improvement or is it the absolute difference that is relevant? How linear is this scale as you interpret it?

My second question relates to what appeared to be a high correlation between the change in ankle-brachial index and your functional outcome scores as presented in your subgroup analysis. As surgeons, we have been criticized for only paying attention to these hemodynamic changes, but it appears from your data that those actually might have a high correlation with the functional outcome. Did you specifically look at the correlation between the change in ankle-brachial index and the relative functional outcomes?

Dr McCarthy. Thank you. The importance of the relative change in the SF36 physical function score at different parts of the scale is not known as far as we could determine. What we assume is that if our group changes from a low score and goes up 28 points, whereas patients with a total hip replacement start at a much higher level and go up 28 points, that our group may have achieved a greater increase. We have thought about it, and we really are not sure.

The r value for ankle-brachial index versus functional status was analyzed in the enrollment data of this study, which was published, and it does correlate. The r value is about 0.18, which is low. The r value for the patients who had change after bypass grafting is quite a bit higher, about 0.6.

Dr John V. White (Philadelphia, Pa). I would like to compliment you on an excellent study and a very interesting collaborative effort.

You had a glimpse, during a short period of 18 months, of patients who had undergone angioplasty, and you looked at their improvement with several measures, such as physical functioning score, the Walking Impairment Questionnaire, and the ankle-brachial index. Did you get a sense in that patient population of the converse: ie, if restenosis was occurring at an angioplasty site, which scores began to reflect that? Did the patients indicate a reduction in distal flow in their physical functioning scores first? Did the ankle-brachial index drop first, or did the Walking Impairment Questionnaire change?

Dr McCarthy. That is an interesting question, but we did not survey the patients in enough detail to answer it. We were examining patients every 6 months. If we had done it once a week, we probably would have had the detail to comment.

Dr Kenneth Granke (Morgantown, WVa). Would you give me your impression or your thoughts on the idea that patients who are treated with claudication who now can exercise better and actually feel better will perhaps do more towards changing or modifying their behaviors that are counterproductive for long-term results? That is, are they more likely to quit smoking, change their diet, and maintain a regular exercise program? Did you get any of that information from this study?

Dr McCarthy. The question is whether patients who are willing to exercise more are also willing to modify their risk factors. That was not something that we were able to analyze, but I presume that it is true.